

**REMARKS**

Receipt of the Office Action dated June 7, 2005 is acknowledged. Claims 2, 5, 7, and 13-17 have been amended herein. Claims 8 and 10 has been canceled. Claims 2-7, 9 and 11-18 are pending. Reconsideration is earnestly solicited in view of the foregoing amendments and the following remarks.

**I. Summary of the Office Action**

The Abstract has been objected to as containing minor informalities. Claims 2-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-5, 7-9, 12-13 and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Salfisberg (2,325,021). Claims 2-5, 7-9, 12-13 and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Schneider (2,976,988). Claims 2-9, 12-13 and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by LeBlanc (3,155,282). Claims 2-7, 9-10, 12-13 and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Nelsen (3,199,437). Claims 2-5, 7-9, 12-15 and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tigner (3,550,764). Claims 2-6 and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Zamarra (3,613,680). Claims 2-5, 7, 9, 12, 14-15 and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Truluck (6,227,359). Claims 2-5, 7-9, 12 and 18 are rejected under 35 U.S.C. § 102(e) as being anticipated by Tu et al. (2003/0152300). Claims 2-18 are rejected under 35 U.S.C. § 102(e) as being anticipated by Shudo et al (2004/0159575).

Claim 10 is rejected under 35 U.S.C. § 103(a) as being unpatentable over any of the previously employed references in view of Shudo et al.

Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Shudo et al. as applied to claim 2 above, and further in view of either Zamarra or Truluck.

Claim 16 is rejected under 35 U.S.C. § 103(a) as being unpatentable over either Tigner or Truluck as applied to claim 14 above, and further in view of Shudo et al.

Claim 10 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not describe din the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

## **II. The Abstract is Proper**

The Abstract has been objected to as containing minor informalities. The Abstract has been amended herein to delete the objected term “means”. Withdrawal of this objection is earnestly solicited.

## **III. Claims 2-7, 9 and 11-18 Clearly Set forth what Applicants Regard as Their Invention**

Claims 2-7, 9 and 11-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2, 5, 7, and 13-17 have been amended herein to overcome the Examiner’s rejections. The claims amendments do not narrow the scope of the pending claims.

With respect to the Examiner’s question as to the meaning of the slash in, for example, the term “ethylene/vinyl” in claims 5 and 15, Applicant respectfully submits that the slash is known to the person having ordinary skill in the art to indicate that the copolymer that contains ethylene and vinyl monomers. Withdrawal of this rejection is earnestly solicited.

## **IV. Claims 2-5, 7, 9, 12-13 and 18 are not Anticipated by the Prior Art**

In order to maintain a rejection under 35 USC § 102, it is required that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). For the reasons set forth herein, none of the prior art references relied upon by the Examiner disclose each and every element as set forth in the claim pending claims. Therefore, withdrawal of these rejections is solicited.

The present invention relates to a product retention package which is especially useful for packaging planar or flat products, such as transdermal delivery systems, patches, bandages, films, sheets, and the like, that maintain the integrity and location such product within the package prior to its removal. By controlling the location of such products within their packaging, damage to the product can be prevented upon opening of the package.

According to the present invention, packaging material is sealed along its edges to form the peripheral seal that extends around the cavity, forming an enclosed product retention package. The retention package includes at least one retention means that extends from the sealed periphery into the cavity. The product located within the cavity of the product retention package is restricted within the certain confines of the cavity. The retention means prevents the product from migrating to a position at which a user will open the product retention package by cutting, tearing or otherwise breaking the periphery seal to access the product within cavity. The retention means prevents movement of product to a position where it could be damaged by opening of package. In this way, retention means thereby protects product when the package is cut or opened along the predetermined position.

As set forth in claim 2, the product retention package includes at least one layer of a product packaging material sealed to form the internal cavity for receiving the product; at least one retention means positioned in a predetermined position relative to the cavity where the at least one retention means restricts movement of the product across a location within the cavity to maintain the position of the product positioned in the cavity distal from a location at which the product package is opened. As set forth in the claims, the at least one retention means is selected from the group consisting of:

- (i) a sealed portion of the product packaging material extending from the sealed periphery formed about the cavity and into the cavity bisected by the location for opening the product package;
- (ii) one or more sealed portions of the product packaging material separate and internal to the periphery formed about the cavity;
- (iii) one or more openings through the product packaging material and sealed along their periphery located internal to the periphery formed about the cavity.

Salfisberg relates to a package with a fold close delivery neck. Salfisberg recites that the bag is folded transversely through the sealing flange and across the discharge neck between the compartment and the tearing flange at fold 9. (See, page 2, left column, lines 44-49). Salfisberg does not disclose a retention means as defined by the claimed invention because none of the structures disclosed by Salfisberg extends from the sealed periphery into the cavity. For at least this reason, Salfisberg does not anticipate claims 2-5, 7, 9, 12-13 and 18.

Schneider relates to a unit dispensing container which is formed with the transversely extending sealed area 18 which divides the total interior space of the container into a first chamber 20 and a second chamber 21. (Col. 3, lines 37-41). Sealed area 18 is divided into two parts spaced at their inner ends to provide transfer passage 23 through which the two chambers 20 and 21 communicate with each other. (Col. 3, lines 42-51). Schneider does not disclose a retention means as defined by the claimed invention because none of the structures disclosed by Schneider "restricts movement of the product across a location within the cavity to maintain the position of the product positioned in the cavity distal from a location at which the product package is opened" as claimed. In fact, in Schneider the product is free to move between chamber 20 and chamber 21. For at least this reason, Schneider does not anticipate claims 2-5, 7, 9, 12-13 and 18.

Leblanc relates to a sprinkler type package for dispensing finely divided granular materials, such as salt or pepper for dispensing on airplanes or the like. According to Leblanc, the package contains a bulk of granular material 12, such as table salt or pepper. (Col. 1, lines 39-43). Leblanc shows that the sheets 10 and 11 are sealed on all four sides as the package is produced. (Col. 1, lines 43-44). The interior of the package includes spaced projections 14 which are spaced and form pockets 16 from which the salt or other material can be readily dispensed by a sprinkling operation. (Col. 1, lines 46-59). Leblanc does not disclose a retention means as defined by the claimed invention because none of the structures disclosed by Leblanc "restricts movement of the product across a location within the cavity to maintain the position of the product positioned in the cavity distal from a location at which the product package is opened" as claimed. In fact, in Leblanc the product 12 is free to move within the package. For at least this reason, Leblanc does not anticipate claims 2-7, 9, 12-13 and 18.

Nelson relates to an infusion apparatus for making cold water coffee infusions. According to Nelson, the apparatus includes a water-impervious outer container 10 which is of sufficient size to handle a suitable amount of water, preferably from about 2-4 quarts water. The device of Nelson also includes an inner container 22 within the container 10. The device also includes inwardly extending projections 26 and projections 24 which extend inwardly from the side walls. (Col. 2, lines 41-47). Product is filled in the inner container 22. Nelson does not disclose a device having an internal cavity in which a product is placed and at least one retention means positioned in a predetermined position into the cavity. In Nelson, the projections 26 and 24 are not positioned in a predetermined position into the cavity 22. Accordingly, Nelson does not disclose a retention means as defined by the claimed invention because none of the structures disclosed by Nelson “restricts movement of the product across a location within the cavity to maintain the position of the product positioned in the cavity distal from a location at which the product package is opened” as claimed. For at least this reason, Nelson does not anticipate claims 2-7, 9-10, 12-13 and 18.

Tigner relates to a tear open device which includes a thickened bead which is integrally formed in a web of synthetic resinous thermoplastic film. The Examiner recites in the Office Action that Tigner discloses a “retention means” 30. According to Tigner, the opening device provided for package 10 generally includes a thickened profile or bead 30 which can be located either at the top or bottom laminate. (Col. 2, lines 53-57). Tigner does not anticipate the instant claims. Tigner merely discloses a tear device having a thickened bead to open the package. Tigner does not disclose a retention means as defined by the claimed invention because none of the structures disclosed by Tigner “restricts movement of the product across a location within the cavity to maintain the position of the product positioned in the cavity distal from a location at which the product package is opened” as claimed. For at least this reason, Tigner does not anticipate claims 2-5, 7, 9, 12-15 and 18.

Zamarra discloses a disposable bag having a flexible and collapsible wall which can be used as the liquid container for a syringe. Zamarra discloses a bag or liquid container which is initially a flat rectangular bag whose side wall has two side portions 1, 2 secured at three edges 3, 4, and 5 with an open mouth at the other edge 6. (Col. 2, lines 10-17). Zamarra recites that the bag can be preloaded with a tablet 7 placed in the bag and the bag walls then being heat-

sealed together in zones 8 outwardly of the perimeter of the tablet. (Col. 2, lines 43-46). When liquid is placed in the bag the tablet dissolves and flows out of the pocket. (Col. 2, lines 46-51). Zamarra does not disclose a retention means as defined by the claimed invention because none of the structures disclosed by Zamarra located at a “location for opening the product package” as claimed. For at least this reason, claims 2-6 and 18 are patentable over Zamarra.

Truluck is directed to a method for the packaging of oil-coated cutting tools, and the resultant packaged product. According to Truluck, an oil-coated cutting tool is packaged by providing a package blank which includes a pair of panels of heat-sealable and oil-impervious material defining a product-containing area between them. The panels have edges defining a package top, bottom and opposite sides, and are permanently sealed to each other along the side-defining and top-defining edges, with an opening along the bottom-defining edges. According to Truluck, to allow the package 12 to be used for storage after it has been initially opened, there is a zipper-like recloseable strip, generally designated 52, which more particularly may be described as an interlocking bead structure 52 which effects an openable and recloseable seal between the panels 18 and 20. (Col. 2, lines 35-40). The interlocking bead structure 52 includes a pair of plastic elements 54 and 56, extruded in appropriate profiles, and thermally bonded to the facing portions of the inner polyester layers 40 of the two panels 18 and 20. (Col. 2, lines 40-46). Truluck does not disclose a retention means as defined by the claimed invention because none of the structures disclosed by Truluck “restricts movement of the product across a location within the cavity to maintain the position of the product positioned in the cavity distal from a location at which the product package is opened” as claimed. For at least this reason, Truluck does not anticipate claims 2-5, 7, 9, 12, 14-15 and 18.

Tu et al. (“Tu”) relates to a pouch 10 that has two sheet walls 11, 12 bonded to each other at peripheral edges thereof. A storage chamber 13 is formed in between the sheet walls. The storage chamber has a main chamber 131 and a sub-chamber 132. The sub-chamber 132 connects to the main chamber 131 and has a smaller size than the main chamber 131. A bonding portion 14 is defined at an area on the pouch beside the sub-chamber 132. Tu does not disclose a retention means as defined by the claimed invention because none of the structures disclosed by Tu “restricts movement of the product across a location within the cavity to maintain the position of the product positioned in the cavity distal from a location at which the product

package is opened” as claimed. In fact, in Tu the product is free to move between the main chamber 131 and the sub-chamber 132. For at least this reason, Tu does not anticipate claims 2-5, 7, 9, 12, and 18.

Shudo et al. (“Shudo”) relates to an envelope 2 having at least one medicated pad or patch 4. The envelope comprises a first panel 6 and a second panel 8. The first panel is shown with its constituent parts splayed apart. The second panel is preferably similarly constructed. Though two pads 4 are shown going into envelope 2, each package typically contains anywhere from one to five pads or patches. (Paragraph 0013) According to Shudo, the package panels are preferably joined around the periphery through heat sealing. The outer margin 10 demarcated by lines 12 are joined in a finished package 2. Line breaks 14 are indicative of a region that may initially left open or unsealed so that a sealing or resealing mechanism 16 can be inserted and then sealed in place as is preferred. The sealing mechanism is preferably a ZIPLOC™ type seal with outer members 18 able to capture and release an inner member 20. (Paragraph 0015). Shudo does not disclose a retention means as defined by the claimed invention because none of the structures disclosed by Shudo “restricts movement of the product across a location within the cavity to maintain the position of the product positioned in the cavity distal from a location at which the product package is opened” as claimed. For at least this reason, Shudo does not anticipate pending claims 2-7, 9 and 11-18.

**V. Claims 10, 11 and 16 would Not Have been Obvious over the Prior Art of Record**

Claim 10 stands rejected as being obvious over Shudo. Claim 10 has been canceled herein. Therefore, the rejection is moot.

Claim 11 stands rejected as being unpatentable over Shudo in view of either Zamarra or Truluck. As set forth above, Shudo relates to an envelope 2 having at least one medicated pad or patch 4. The envelope comprises a first panel 6 and a second panel 8. Shudo does not disclose that the device includes “at least one retention means restricts movement of the product across a location within the cavity to maintain the position of the product positioned in the cavity distal from a location at which the product package is opened” as claimed. As set forth above, there is nothing in either Zamarra or Truluck to overcome the deficiency in Shudo. For at least this reason, claim 11 is patentable over this combination of references.

Claim 16 is rejected under 35 U.S.C. § 103(a) as being unpatentable over either Tigner or Truluck in view of Shudo et al. As set forth above, neither Tigner nor Truluck disclose or suggest a device that includes “at least one retention means restricts movement of the product across a location within the cavity to maintain the position of the product positioned in the cavity distal from a location at which the product package is opened” as claimed. As set forth above, there is nothing in Shudo to overcome the deficiency in Shudo. For at least this reason, claim 16 is patentable over this combination of references.

**VI. The rejection of claim 10 under 35 U.S.C. § 112, first paragraph is Moot**

Claim 10 stands rejected under 35 U.S.C. § 112, first paragraph. While the applicant disagrees with the Examiner’s position, solely in an effort to further prosecution, claim 10 has been canceled herein. Therefore, the rejection is moot. The applicant reserves the right to pursue the subject matter of claim 10 in further applications.

**VII. Conclusion**

In view of the above amendments and remarks, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

By 

Jeremy A. Cubert

Registration No.: 40,399

DICKSTEIN SHAPIRO MORIN & OSHINSKY  
LLP

2101 L Street, NW  
Washington, DC 20037  
(202) 785-9700  
Attorney for Applicants